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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,109	03/19/2004	Sergio Landau	BJT 353	8495

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EXAMINER	
MENDEZ, MANUEL A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
03/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,109	LANDAU, SERGIO	
	Examiner	Art Unit	
	Manuel A. Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. **Claims 1-12**, drawn to a needle-free injection system, comprising: a nozzle including a fluid chamber and an injection orifice; and a filling adapter secured to the nozzle and configured to couple the nozzle with an external supply of injectable fluid to enable filling of the fluid chamber with injectable fluid, where the needle-free injection system is configured to prevent delivery of an injection from the injection orifice into an injection site until the filling adapter's ability to enable filling of the fluid chamber has been disabled, classified in class 604, subclass 72.

II. **Claims 13-28**, drawn to a needle-free injection system, comprising: a nozzle including a fluid chamber and an injection orifice in fluid communication with the fluid chamber; and a filling adapter frangibly attached to the nozzle and configured to enable attachment of an external supply of injectable fluid to the nozzle to enable filling of the fluid chamber with injectable fluid, classified in class 604, subclass 523.

III. **Claims 29-32**, drawn to a needle-free injection system, comprising: a nozzle including a fluid chamber and an injection orifice; and a filling adapter configured to couple the nozzle with an external supply of injectable fluid to enable filling of the fluid chamber with injectable fluid, the filling adapter being frangibly attached to the nozzle relative to the

injection orifice so as to interfere with delivery of an injection of injectable fluid from the fluid chamber out through the injection orifice to an injection site, classified in class 604, subclass 264.

IV. **Claims 33-45**, drawn to a needle-free injection system, comprising: a nozzle including a fluid chamber and an injection orifice adapted to enable delivery of pressurized injections of fluid from the fluid chamber out through the injection orifice into an injection site; and a filling adapter attached to the nozzle and configured to couple an external supply of injectable fluid to the nozzle to enable the fluid chamber to be filled with injectable fluid, where the filling adapter prevents delivery of an injection unless the filling adapter is detached from the nozzle, and where such detachment of the filling adapter disables the ability to couple the external supply of injectable fluid to the nozzle, classified in class 604, subclass 523.

V. **Claims 46-49**, drawn to a needle-free injection system, comprising: a disposable single-use nozzle assembly, including a fluid chamber in fluid communication with an injection orifice, and a plunger slidably and sealingly disposed within fluid chamber so that fluid within the fluid chamber is forcibly expelled out through the injection orifice along an injection axis upon forcible advancement of the plunger within the fluid chamber; and an ejector mechanism to which the nozzle assembly may be selectively attached, including: a firing member configured to retract

and advance during arming and discharging of the ejector mechanism, the firing member being configured to push the plunger forward during discharging of the ejector mechanism; and a plunger coupling device secured to the firing member and movable between a coupled position and a released position, where in the coupled position the plunger coupling device couples the plunger to the firing member to enable retraction of the plunger upon retraction of the firing member, and where the ejector mechanism is configured so that the plunger coupling device is automatically moved into the released position during advancement of the firing member, to thereby facilitate removal of the nozzle assembly from the ejector mechanism after delivery of an injection, classified in class 604, subclass 264.

VI. **Claims 50-54**, drawn to a method of delivering a needle-free injection to an injection site by forcibly ejecting fluid from a fluid chamber of a nozzle and out through an injection orifice of the nozzle, the method comprising: coupling an external supply of injectable fluid to a filling adapter that is attached to the nozzle; filling the fluid chamber with injectable fluid by causing injectable fluid to flow from the external supply through the filing adapter and injection orifice and into the fluid chamber; breaking the filling adapter away from the nozzle; and forcibly expelling fluid out of the fluid chamber through the injection orifice along an injection axis, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombinations have separate utility as evidenced by the structural variations disclosed in Groups I-V above. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, since claim 50 does not disclose all the structural elements disclosed in the product independent

claims in Groups I-V, the method can be practiced with another materially different product.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM